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| EXAMINER | |
|---|---|
| PAK, JOHN D | |

| ART UNIT | PAPER NUMBER |
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| 1616 | |

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

TH

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/722,811 | HENSLEY ET AL. | |
| | Examiner | Art Unit | |
| | JOHN PAK | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *11,13,14,16-20,22,41 and 43-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,13,14,16-20,22,41 and 43-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 11, 13-14, 16-20, 22, 41 and 43-48 are pending in this application.

Applicant is advised of a minor spelling error: "carrageegan" in claim 1 should be spelled as --- carrageenan --- .

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 13-14, 16-20, 22, 41 and 43-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) Independent claim 11 has been amended to recite the new language, "a salt agent to increase diffusion of the active substance through mucous" (emphases added). The phrase "through mucous" is confusing. Is it "through mucous membrane in the nasal cavity" (spec. p. 14, line 13), "through mucous on the epithelial membrane" (spec. p. 5, line 25) or "through mucous in the nasal passage" (spec. p. 17, line 8)?

(2) The amendatory Markush language for the thickening agent is indefinite -- "guar gum, and hydroxycellulose, methylcellulose ... and other carbohydrates" (emphases added).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 13-14, 16-20, 22, 41 and 43-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims

contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This ground of rejection is based on the determination that there is insufficient descriptive support from the originally filed disclosure for the amendatory feature, "a salt agent to increase diffusion of the active substance through mucous" (emphases added).

The originally filed disclosure that *may* be relevant to a salt agent that increases diffusion of the active substance through mucous is as follows (spec. p. 17, first full paragraph & p. 21, lines 21-27):

> **The rate of diffusion of an active substance through mucous in the nasal passage can be increased by using in the gel composition an agent like zinc or salt which facilitate the breakup and drying of mucous in the nose or by using in the gel composition a component which actually facilitates travel of an active substance through mucous. Mucous is a protein and has different properties than the nasal epithelial membrane. Agents like zinc or salt can be included in the nasal gel in concentrations in the range of 0.000001% to 5% by weight.**
>
> **EXAMPLE 23**
>
> **Example 22 is repeated except that the gel composition of Example 1 also includes 1.0% by weight NaCl and that the weight percent of the purified water in the gel composition is 96% instead of 97%. The weight percent of glycerin, carbopol, and zinc gluconate in the gel composition of Example 1 remain the same. The salt is included in the gel composition in order to facilitate the diffusion of zinc through the layer of mucous.**

Even though specification page 17 discloses "salt," note that this is not the same as "a salt agent" or "a salt" that increases diffusion, as claimed. This is a significant difference because without more, "salt" can refer exclusively to NaCl. Within the context of this invention, specification Example 23 on page 21 is evidence that applicant originally provided written description for sodium chloride only, i.e. the common salt, as the "salt" (which is not a zinc salt) that increases diffusion of the active substance through the mucous in the nasal cavity or otherwise.

For these reasons, the claims are rejected as lacking in adequate descriptive support.

Due to applicant's amendment to independent claim 11, which introduces new matter into the claims, all outstanding prior art-based grounds of rejection are hereby withdrawn. If and when applicant removes the new matter, applicant is hereby given advance notice that said grounds of rejection may be reinstated as appropriate.

Effective filing date of the claims, as presently amended

Before applying any prior art, determination of effective filing date is needed. Here, applicant has amended the claims to introduce new matter, which fails to find adequate descriptive support from the originally filed disclosure of this application or the parent application. Thus, the presently amended claims are not supported by the disclosure of the parent application; and consequently the effective filing date of this application cannot be 9/1/1998, the filing date of the parent application. For lack of a

better date regarding new matter, the effective filing date for the purpose of this Office action will be taken as the filing date of this application, 11/25/2003.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 13, 14, 19, 20, 22, 41, 43-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Fust (US 6,344,210).

Fust explicitly discloses a composition for freshening sinus cavities that contains the following ingredients (column 9):

--- see next page ---

| RANGE | INGREDIENT | APPLICATION | PER-CENTAGE |
|---|---|---|---|
| 0.1 to 2% | Sodium chloride | Osmotic agent | 0.650 |
| 0.1 to 5% | Sodium borate | Buffering agent | 0.100 |
| 0.1 to 9% | Alcohol SD | Solubilizing agent | 0.090 |
| 0.001 to 2% | Edetate disodium | Preservative | 0.050 |
| 0.1 to 3% | Glycerin | Solubilizing agent | 0.001 |
| 0.001 to 5% | Polysorbate 80 ™ | Surfactant | 0.045 |
| 0.001 to 5% | Poloxamer 407 ™ | Antiseptic | 0.030 |
| 0.001 to 5% | Domiphen bromide | Antiseptic | 0.030 |
| 0.001 to 5% | Cetylpyridinium chloride | Anti-infective/ Anti-Fungal | 0.040 |
| 0.1 to 2% | Sorbitol | Sweetener | 0.002 |
| 0.1 to 2% | Sodium saccharin | Sweetener | 0.002 |
| 0.1 to 5% | Aromatic component | Masking agent | 0.005 |
| 0.001 to 5% | Zinc acetate/zinc chloride | Healing agent | 0.040 |
| | Deionized water | Solvent (vehicle) | <100% (W/W %) |

The following is a feature-by-feature discussion of applicant's claims.

"about" 0.185 to 2.8 wt% or "about" 0.9 to 2 wt% zinc salt: Fust discloses 0.001 to 5 wt% zinc acetate or zinc chloride. Applicant's range is clearly envisaged within Fust's range.

"about" 4 to 60 mM zinc ion or "about" 20 to 44 mM zinc ion: 4 to 60 mM zinc ion is actually the equivalent of about 0.185 to 2.8 wt% zinc salt when the zinc salt is zinc gluconate. Hence, the mM feature is another way of expressing the same or similar percentage weight feature. The numbers calculate and correspond the same way for the 20 to 44 mM feature and 0.9 to 2 wt% zinc salt. For the reasons that the above

weight amounts of the zinc salts are anticipated, the zinc mM features are also anticipated.

A salt agent to increase diffusion of the active substance: Fust's sodium chloride and sodium borate are salts. Since "a salt agent" is claimed and sodium chloride is clearly within this claim language, this feature is met.

Fluid: Fust's alcohol, glycerin and water meet this feature.

Thickening agent, 0.1 to 3 wt% thickening agent: sorbitol is a carbohydrate.[1] Applicant recites carbohydrate as a thickening agent. This feature is met since Fust explicitly discloses 0.1 to 2 wt% sorbitol.

75-99.999 wt% carrier or water: the amount of water + glycerin or water alone in Fust's composition meets this feature. See above table.

0.000001 to 5 wt% glycerin: Fust's glycerin is present at 0.1 to 3 wt%.

Permeation enhancer: Fust explicitly discloses 0.1 to 3 wt% glycerin and 0.001 to 2 wt% edetate dosodium (i.e. EDTA disodium). Applicant acknowledges that glycerin and EDTA have permeation enhancing properties – see specification page 9, lines 10-13 and paragraph bridging pages 15-16. This feature is thereby met.

[1] This is a factual statement. No further evidence is required when the Examiner makes a factual statement regarding a common substance. However, if applicant has any doubt as to this statement, Pediatrics, Vol. 95(3), March 1995, page 342, left column, last paragraph is provided: "The major carbohydrates present in juice are fructose, glucose, and sorbitol."

Method of treating a cold by administering the composition to a nasal membrane:

Treatment of the common cold is explicitly disclosed (column 6, lines 29-42). Since Fust's composition is administered "into the nostrils and therethrough" (column 3, lines 29-30), this claim feature is met.

A system for applying the composition to a nasal membrane:

Fust explicitly discloses an inhaler or atomizer-type container for introducing the composition through the nose (column 3, lines 31-34), so this feature is met.

For these reasons, the claims are anticipated.

Claims 11, 13-14, 19 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Hersh (US 5,906,811).

Hersh explicitly discloses the following compositions (columns 20-21):

EXAMPLE 5

The following composition was prepared for administering the active ingredients as a gel (expressed as % by weight):

| | |
|---|---|
| glycerin | 42.0 |
| poloxamer | 18.0 |
| ascorbic acid | 2.0 |

--- continued on the next page ---

| | |
|---|---|
| sodium lauryl sulfate | 1.2 |
| natural peppermint oil | 1.0 |
| alpha tocopherol | 0.75 |
| green tea | 0.5 |
| calcium lactate | 0.25 |
| selenomethionine | 0.20 |
| sodium fluoride | 0.20 |
| L-glutathione | 0.10 |
| coloring agent | 0.10 |
| deionized water | balance |
| xylitol sweetener | 15.00 |
| zinc acetate | 0.15 |

"A composition for delivering an active substance to a nasal membrane": Note that the rejected claims are directed to compositions or a "system." Hence, given that Hersh's water + glycerin + oil containing gel composition could be delivered to a nasal membrane, this feature is met.

"about" 0.185 to 2.8 wt% zinc salt: Hersh's 0.15 wt% zinc acetate meets this feature.

"about" 4 to 60 mM zinc ion: Hersh's 0.15 wt% zinc acetate approximates to about 8 mM zinc ion concentration.

A salt agent to increase diffusion of the active substance: Hersh's sodium lauryl sulfate, calcium lactate and sodium fluoride are all salts. Since "a salt agent" is claimed and sodium chloride is clearly within this claim language, similar salts as those disclosed by Hersh would meet this claim feature.

Fluid: Hersh's glycerin, peppermint oil and water meet this feature.

Thickening agent: xylitol is a carbohydrate. Applicant recites carbohydrate as a thickening agent. This feature is met.

75-99.999 wt% carrier: the amount of glycerin + water + xylitol in Hersh's composition meets this feature. See above table.

Permeation enhancer: Hersh explicitly discloses glycerin. Applicant acknowledges that glycerin has permeation enhancing properties (specification page 9, lines 10-13). This feature is thereby met.

For these reasons, the claims are anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 13-14, 16-20, 41, 43-45 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hersh.

Hersh's teachings have been fully discussed above and the discussion there is incorporated herein by reference. Additionally with respect to this ground of rejection under section 103(a), it is noted that Hersh further teaches the use of zinc broadly (i.e. not just zinc acetate) and antimicrobial activity at concentration ranges of 0.1-3 wt%. See column 8, line 18; column 14, lines 46-49 & 65-66. Zinc gluconate is used in

several of Hersh's examples (Examples 1-2) and disclosed as interchangeable (column 18, lines 66-67). With respect to a gel formulation, incorporation of bicarbonates and "thickening agents" are disclosed, such as 0.5-5 wt% carrageenans, hydroxyethyl-cellulose or methylcellulose (column 12, lines 27-35).

The following is a discussion of each of the claim features.

"A composition for delivering an active substance to a nasal membrane": Note that the rejected claims are directed to compositions or a "system." Hence, given that Hersh's gel composition could be delivered to a nasal membrane, this feature is met.

"about" 0.185 to 2.8 wt% zinc salt: Hersh's 0.15 wt% zinc acetate example meets this feature.

about 0.185 to 2.8 wt% zinc gluconate: Hersh discloses the interchangeability of zinc gluconate and zinc acetate. This feature is thereby fairly suggested.

"about" 0.9 to 2 wt% ionizable zinc salt: Hersh utilizes zinc salts for antimicrobial purposes (column 14, lines 64-65) and discloses concentrations of 0.1-3 wt% as being suitable for activity (column 14, line 66). Applicant's concentration range is therefore fairly suggested.

"about" 4 to 60 mM zinc ion: Hersh's 0.15 wt% zinc acetate approximates to about 8 mM zinc ion concentration.

"about" 20-44 mM zinc ion: since Hersh discloses 0.1-3 wt% zinc salt, wherein the exemplified 0.15 wt% zinc acetate approximates to about 8 mM zinc ion, the instant claim feature is fairly suggested by Hersh's disclosure.

A salt agent to increase diffusion of the active substance: Hersh's sodium lauryl sulfate, calcium lactate and sodium fluoride are all salts. Since "a salt agent" is claimed and sodium chloride is clearly within this claim language, similar salts as those disclosed by Hersh would meet this claim feature.

Thickening agent, 0.000001 to 5 wt%: xylitol is a carbohydrate. Applicant recites carbohydrate as a thickening agent. Feature of claim 11 is fairly suggested by xylitol.

Alternatively, xylitol can be categorized as a flavorant and Hersh's thickening agent is 0.5-5 wt% carrageenans, methylcellulose or hydroxyethylcellulose (column 12, lines 32-34).

Fluid: Hersh's glycerin, peppermint oil and water meet this feature.

75-99.999 wt% carrier: the amount of glycerin + water + xylitol in Hersh's composition meets this feature. See above table.

Permeation enhancer: Hersh explicitly discloses glycerin. Applicant acknowledges that glycerin has permeation enhancing properties (specification page 9, lines 10-13). This feature is thereby met.

A system for applying the composition to a nasal membrane: Nothing more than an applicator and the composition is required in applicant's system, so a mere container and a means for applying Hersh's gel would meet this claim

feature. One having ordinary skill in the art would have been motivated to provide the gel in a container and then use some means to apply the gel to the route of administration. The "system" is thereby fairly suggested.

In sum, one having ordinary skill in the art would have recognized from Hersh's illustrative gel formulation Example 5 that the components can be modified in accordance with Hersh's complete teachings. Suitability of different concentrations of antimicrobial zinc salts such as zinc gluconate or zinc acetate would have been suggested from the antimicrobial needs of the particular end use. Hersh suggests the use of 0.5-5 wt% thickening agents such as carrageenans and cellulose derivatives such as hydroxyethylcellulose when the formulation is a gel, so incorporation of such agents would also have been fairly suggested from the need to thicken the gel as appropriate.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited reference.

Claims 11, 13, 16-18, 19-20, 20, 22, 41-45, 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eby, III (Re. 33,465, hereinafter referred to as "Eby") in view of ES 2095183, HCAPLUS abstract 1994:638216 and DE 3431727[2].

Eby teaches reduction in the duration of common cold symptoms such as nasal drainage, nasal obstruction, sore throat, fever, cough, which are the result of upper respiratory infection (column 2, lines 57-64) by applying to the nasal mucosal membrane a zinc compound (column 2, lines 64-68). Nasal sprays, nasal drops, nasal ointments, nasal washes and nasal injections are taught (column 3, lines 3-7). Zinc gluconate is taught (column 3, line 24).

ES 2095183 discloses a drug delivery system composed of aqueous preparations that have a liquid form at room temperature but become gels at body temperature and adhere to the nasal mucosa (see the English abstract, HCAPLUS abstract 1997:283905). Less than 1% bioadhesive polymer such as hydroxypropyl cellulose and sodium chloride for isotonicity is disclosed (id.). Advantage of the gel intranasal delivery is controlled delivery (id.).

HCAPLUS abstract 1994:638216 discloses that bioavailability of nasally applied drugs is reduced by nasal mucociliary clearance, so nasal solutions contain polymers as thickeners to prolong the time between drug and the mucosa. Methyl hydroxypropyl cellulose and gellan gum (polysaccharide, i.e. a carbohydrate) are known thickeners in

[2] English translation is provided herewith. All page and line numbers are to the English translation document.

solutions of drugs that are applied nasally. The gellan gum is advantageous in that its viscosity increases when physiological level of cations are present.

DE 3431727 discloses that nasally applied zinc gluconate for treating viral ailments such as the common cold is at a concentration of 0.1 to preferably 2% (page 3, claims 1-2; page 6, last paragraph). 2% zinc gluconate nose spray is exemplified (page 7, line 6 from the bottom).

Eby does not expressly disclose every claim limitation or feature recited in the instant claims. Discussion of each feature and suggestion from the cited prior art is set forth below.

"A composition for delivering an active substance to a nasal membrane":

Eby provides the motivation to deliver Zn gluconate nasally. Nasal sprays, nasal drops, nasal ointments, nasal washes and nasal injections are taught (column 3, lines 3-7).

"about" 0.185 to 2.8 wt% zinc gluconate, "about" 0.9 to 2 wt% ionizable zinc salt, "about" 4 to 60 mM zinc ion, "about" 20-44 mM zinc ion:

Although Eby does not expressly disclose these concentrations, Eby teaches the nasal administration of zinc to treat the symptoms of the common cold. DE 3431727 provides the motivation to nasally administer zinc gluconate for treating viral ailments such as the common cold at a concentration of 0.1 to 2% (page 3, claims 1-2; page 6, last paragraph). 0.1% zinc gluconate calculates to about 2.2 mM and 2% zinc gluconate calculates to about 44 mM.

Motivation to select the drug delivery system of ES 2095183:

Eby does not provide a specific formulation disclosure for nasal administration. Hence, the ordinary skilled artisan would have looked to nasal delivery technology that was available before applicant's effective filing date. ES 2095183 teaches that its aqueous drug delivery preparation is a liquid at room temperature but gels at body temperature and adheres to the nasal mucosa, thereby providing controlled delivery of active drugs. The ordinary skilled artisan would have been motivated to formulate zinc gluconate as taught by ES 2095183 with the expectation that zinc gluconate would be conveniently administered as a liquid that gels in the nasal mucosa to provide controlled delivery of the zinc to treat the common cold. The ordinary skilled artisan would have been further motivated from HCAPLUS abstract 1994:638216 that bioadhesives such as those utilized in ES 2095183 advantageously prolong the contact time between the mucosa and the delivered drug.

A salt agent to increase diffusion of the active substance: The drug delivery formulation of ES 2095813 contains sodium chloride to provide isotonicity.

Thickening agent, 0.000001 to 5 wt%: The drug delivery formulation of ES 2095813 contains bioadhesive polymers such as cellulose derivatives at an amount that is less than 1%. The example on page 3, column 4, lines 35-49 of ES 2095183 discloses 0.2 g of hydroxypropylmethylcellulose in 100 ml of water, i.e. 0.2 wt%.

Hydroxyethylcellulose as the thickening agent: From the general bioadhesive teaching to the specific hydroxypropylcellulose exemplified by ES 2095813,

hydroxyethylcellulose would have been an obvious modification since both cellulose derivatives are structurally similar cellulose ethers. Motivation to make the modification arises from the advantages of utilizing similar bioadhesive polymers to provide controlled delivery of the active substance.

75-99.999 wt% carrier such as water: The example on page 3, column 4, lines 35-49 of ES 2095183 discloses 12.15 g of ingredients in water to make up 100 ml. Such amount of water falls within applicant's water amount.

Permeation enhancer: The drug delivery formulation of ES 2095813 contains benzyl alcohol. An alcohol would provide solvent properties and would thus provide permeation enhancement.

A system for applying the composition to a nasal membrane: Nothing more than an applicator and the composition is required in applicant's system, so a mere container and a means for applying Hersh's gel would meet this claim feature. One having ordinary skill in the art would have been motivated to provide the gel in a container and then use some means to apply the gel to the route of administration. The "system" is thereby fairly suggested.

In sum, the ordinary skilled artisan would have been motivated to select the nasal delivery formulation of ES 2095183 to nasally deliver Eby's zinc gluconate to treat symptoms of the common cold because said nasal delivery formulation would have been expected to provide the advantages of controlled delivery and prolonged contact time in the mucosa. Inclusion and utilization of all other ingredients and features are

fairly suggested as discussed above. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11, 13, 17-20, 22, 41 and 44-45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,673,835 in view of ES 2095183 and DE 3431727.

Patented claims 1-6 are directed to methods of delivering zinc into the blood by providing a mixture of zinc, 1.5 wt% zinc gluconate for example, and 75-99.999 wt% at least one carrier to the nasal membrane. Up to 5 wt% carbohydrate thickener is included in the mixture (claims 4-5).

ES 2095183 discloses a drug delivery system composed of aqueous preparations that have a liquid form at room temperature but become gels at body temperature and adhere to the nasal mucosa (see the English abstract, HCAPLUS abstract 1997:283905). Less than 1% bioadhesive polymer such as hydroxypropyl cellulose and sodium chloride for isotonicity is disclosed (id.). Advantage of the gel intranasal delivery is controlled delivery (id.). 0.2 wt% hydroxypropylmethylcellulose in water is exemplified (page 3, column 4, lines 35-49).

DE 3431727 discloses that nasally applied zinc gluconate for treating viral ailments such as the common cold is at a concentration of 0.1 to preferably 2% (page 3, claims 1-2; page 6, last paragraph). 2% zinc gluconate nose spray is exemplified (page 7, line 6 from the bottom).

The patented claims in U.S. Patent No. 6,673,835 do not expressly recite "a salt agent to increase diffusion of the active substance through mucous." However, ES 2095183 discloses the advantage of adding sodium chloride for isotonicity, so

incorporation of sodium chloride to the zinc composition utilized in said patented claims is fairly suggested. The zinc concentration features of the instant claims correspond or overlap with those of said patented claims. For example, the 1.5 wt% zinc gluconate (patented claim 3) calculates to about 33 mM. The broader ranges are fairly suggested by the concentration range of DE 3431727 for the same cold-treating utility.

Further, from the general bioadhesive teaching to the specific hydroxypropylcellulose exemplified by ES 2095813, hydroxyethylcellulose would have been an obvious modification since both cellulose derivatives are structurally similar cellulose ethers. Motivation to make the modification arises from the advantages of utilizing similar bioadhesive polymers to provide controlled delivery of the active substance.

75-99.999 wt% carrier such as water is fairly suggested by the same amount carrier set forth in the patented claims and the use of water carrier in the nasal formulation of ES 2095813. A generalized permeation enhancer would have been an advantageous inclusion because better permeation would provide improved delivery of the zinc active substance. As for a "system for applying the composition to a nasal membrane," nothing more than an applicator and the composition is required in applicant's system, so a mere container and a means for applying the gel as set forth by the patented claims and modified as explained herein would meet this claim feature. One having ordinary skill in the art would have been motivated to provide the gel in a

container and then use some means to apply the gel to the route of administration. The "system" is thereby fairly suggested.

For these reasons, one of ordinary skill in the art would have recognized the claimed invention as an obvious variation of the invention claimed in claims 1-6 of U.S. Patent No. 6,673,835 in view of the cited secondary references.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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